

(1) Publication number:

0 455 324 B1

(12)

## **EUROPEAN PATENT SPECIFICATION**

- (45) Date of publication of patent specification: 07.06.95 (51) Int. Cl.6: A61F 13/00
- (1) Application number: 91301430.4
- 2 Date of filing: 22.02.91
- 6 Burn dressing product.
- Priority: 02.05.90 US 517837
- Oate of publication of application: 06.11.91 Bulletin 91/45
- 49 Publication of the grant of the patent: 07.06.95 Bulletin 95/23
- Designated Contracting States:
  AT BE CH DE DK FR GB GR IT LI LU NL SE
- 69 References cited: EP-A- 0 309 309 EP-A- 0 356 614 WO-A-90/03155 US-A- 4 793 337 US-A- 4 909 244

- Proprietor: New Dimensions in Medicine, Inc. (a Delaware Corporation)
   3040 East River Road
   Dayton, Ohio 45439 (US)
- Inventor: Cartmell, James V. 8275 Rhineway Centerville, Ohio 45458 (US) Inventor: Wolf, Michael L. 209 West Hayes Street West Milton, Ohio 45383 (US) Inventor: Allaire, Michael J. 336 Firwood drive, Apt.C. Dayton, Ohio 45419 (US) Inventor: Sturtevant, Wayne R. 20 South Johanna Drive Centerville.

Ohio 45458 (US)

Representative: Warren, Anthony Robert et al BARON & WARREN, 18 South End, Kensington London W8 5BU (GB)

422 274 O J

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

#### Description

This invention relates to burn dressings and, more particularly, to a flexible burn dressing product containing a hydrogel substance particularly useful in the active therapy of thermal, chemical, electrical, and similar wounds conventionally classified as "burns."

1

Burn injuries require a unique combination of therapy and dressing because the physiologic functions of the skin are absent or, at best, materially impaired. Body fluids and their essential components are continuously lost. The natural barrier characteristics normally provided by one's skin, of preventing invasion of harmful micro-organisms and other noxious agents, are no longer functional. Potentially fatal infections are a continuous serious threat to burn patients. The debris reservoir of necrotic tissue saturated with seeping wound exudate remains on the wound site, harboring and nourishing agents of infection whose presence and by-products interfere with the regeneration of viable, functioning, epithelial tissue having skin organ properties.

The basic tenets of therapy required to treat burns are specifically directed toward providing and improving the impaired physiologic functions of the skin. Of initial concern is the removal of the necrotic products of injury. Also of great importance is providing a barrier to bacterial invasion from the environment while controlling the contamination already present. Finally, burn therapy is directed toward stemming the loss of vital body fluids.

Burn injuries and the like have been treated at various stages by application of sterile coverings in the form of pastes or creams, gauze wrappings, natural and synthetic membranes, films, or sponges. Except in the case of skin grafting, the approach has been to prevent adhesion of the covering materials to the wound site while encouraging adhesion of the burn exudate to the covering materials

One existing burn exudate absorption method is to apply a polyurethane polymer composition to the burn site. As disclosed in Gould, U.S. Patent No. 4,156,066, and Gould, U.S. Patent No. 4,156,067, issued May 22, 1979, a polyurethane polyether resin may be applied to a burn as a powder. However, powder tends to attract fluids from the burn wound and deteriorates as the wound fluids are absorbed, resulting in lumping and uneven application. Additionally, such deteriorated lumps are difficult to remove from a burn site without damaging new cell tissue at the burn site.

A burn dressing which attempts to minimize fluid loss from the burn site is disclosed in U.S. Patent No. 3,648,692, issued to Wheeler on March

14, 1972. The Wheeler burn dressing discloses an open cell foam material which can be applied directly to a burn wound site. However, while it is desirable to stem the loss of vital body fluids from the already weakened patient, the Wheeler burn dressing eliminates or minimizes the loss of all fluids, even fluids contaminated with necrotic tissue, from the burn site. Also, new cell tissue forming at the burn site may adhere to the spongelike material, making it difficult to remove the burn dressing from the burn site without damaging new cell tissue. Consequently, the Wheeler burn dressing serves merely as a sedentary covering for allowing the burn to heal, rather than actively expediting the healing.

Aqueous moisture absorbing materials, such as a polyethylene glycol liquid curing agent as disclosed in Spence, U.S. Patent No. 4,226,232, issued October 7, 1980, are easier to remove from the wound site, but cannot be sterilized by irradiation due to the formation of free radicals within the aqueous material. Another aqueous absorbing material used to absorb wound exudate, hydrophilic polymer, is disclosed in Rawlings et al, U.S. Patent No. 4,657,006, issued April 14, 1987. In the Rawlings et al reference, a wound dressing is described which comprises a hydrophilic polymer having moisture vapor permeability characteristics. A problem with the Rawlings et al wound dressing is that the wound exudate absorbed by the hydrophilic polymer hardens the polymer, allowing pockets to develop between the polymer and the wound, providing an excellent environment for bacteria proliferation.

Known aqueous moisture absorbing wound dressing systems have additional problems, in that the aqueous material is generally contained in the center portion of a wound dressing, with a bulky adhesive border, such as a foam border. Problems with such borders include decreased comfort, conformity and adhesion as well as the existence of a "lifting edge" that can catch on clothes or bed sheets, thereby exposing the wound to bacteria and infection. In addition, burn sites typically have very little healthy skin to which such a dressing may be adhered.

An existing method of overcoming the problems associated with bulky wound dressings is disclosed in Potts. U.S. Patent No. 3,526,224 issued September 1, 1970. The Potts reference discloses a wound dressing comprised of an elastomeric polyurethane film which acts as a second skin during the wound healing process. One problem with the Potts wound dressing, however, is that the "second skin" requires surgery to remove it after the wound has healed.

Quarfoot US Patent No 4 909 244 discloses a wound dressing comprising a layer consisting es-

sentially of a hydrogel for placing on a wound, an intermediate layer disposed over said hydrogel layer and an outer oxygen and vapour-permeable layer for transpiration of fluid diffusing through the dressing. The dressing is secured to the wound by an adhesive layer and/or a tacky hydrogel either of which is disadvantageous in that they contribute to wound trauma upon removal of the dressing.

Hence, it would be desirable to provide a burn dressing which eliminates or minimizes vital and healthy fluid loss from a burn site while simultaneously removing contaminated or infected wound fluids. It would also be desirable to provide a burn dressing product which could be readily available for application to a burn wound. It would further be desirable to provide such a burn dressing which contains wound debridement characteristics but does not adhere to the burn site, thereby providing means to expedite healing. In addition, it would be desirable to provide a burn dressing which could be removed neatly and, more importantly, without adhering to the new cell tissue forming at the burn site. Finally, it would be desirable to provide such a burn dressing product which could be comfortably applied to any area on a body. 1...

The present invention meets these needs by providing a thin-film burn dressing containing an aqueous hydrogel material, partially impregnated in a reticulated layer which may be of any suitable material including foam, scrim or non-woven material. The present invention also provides a method of manufacture and application of a burn dressing product which includes the burn dressing. The burn dressing product herein can be manufactured to any desirable size to provide a wound debridement dressing for any size burn site. The burn dressing herein is adhesive only to the extent that exuding wound fluids are absorbed, and non-adhesive upon removal from the burn site.

According to one aspect, the present invention provides a burn dressing product for a burn, comprising: a burn dressing including a bacterial barrier layer having a first side and a second side, a reticulated layer combined with a hydrogel material and having a first side and a second side, said second side of said reticulated layer being secured to said bacterial barrier layer, a hydrogel material layer on said first side of said reticulated layer; and a release liner overlying said hydrogel material layer and secured to said first side of said reticulated layer by means of said hydrogel material layer characterised in that said hydrogel material comprises from 15% to 30% by weight of a polyhydric alcohol selected from a group consisting of polypropylene glycol, polyethylene glycol and glycerine, from 8% to 14% by weight of an isophorone diisocyanate terminated prepolymer, from 5% to 10% by weight of a polyethylene oxide based

diamine, up to 1% by weight of a salt, and the balance water, that said reticulated layer is sufficiently absorbent to be impregnated with said polyurethane hydrogel material and that said hydrogel material retains its gel-like consistency so as to allow for non-traumatic removal of said burn dressing.

The present invention also provides a method of manufacturing a burn dressing product for a burn wound comprising the steps of providing a release liner; providing a reticulated layer, said reticulated layer having a first side and a second side; providing a bacterial barrier layer, said bacterial barrier layer having a first side and a second side; laminating said second side of said reticulated layer to said first side of said bacterial barrier layer; combining said reticulated layer with a hydrogel material, said hydrogel material forming a smooth hydrogel material layer on said first side of said reticulated layer; applying said release liner to said first side of said smooth hydrogel layer wherein said smooth hydrogel material layer is located between said reticulated layer and said release liner characterised in that said hydrogel material comprises from 15% to 30% by weight of a polyhydric alcohol selected from the group consisting of polypropylene glycol, polyethylene glycol and glycerine, from 8% to 14% by weight of an isophorone diisocyanate terminated prepolymer, from 5% to 10% by weight of a polyethylene oxide based diamine, up to 1% by weight of a salt, and the balance water, said reticulated layer is sufficiently absorbent to be impregnated with said polyurethane hydrogel material and that said hydrogel material retains its gel-like consistency so as to allow for non-traumatic removal of said burn dressing so as not to destroy new cell tissue forming at a burn site.

Since the impregnated layer and aqueous hydrogel are extremely flexible and pliable, the method of manufacturing the burn dressing product may further include the step of providing a dimensionally stable backing member to maintain the burn dressing in its desired shape until the burn dressing product is applied to a burn site. The dimensionally stable backing member is applied to the second side of the bacterial barrier layer, wherein an adhesive layer is located between the second side of the bacterial barrier layer and the dimensionally stable backing member. In a preferred embodiment of the invention, the bonding layer preferably has stronger bonding qualities than the adhesive layer so as to allow removal of the dimensionally stable backing member from the bacterial barrier layer after application of the burn dressing product to the burn, while maintaining adhesion between the hydrogel material layer and the skin of a patient.

Directly contacting the burn is the hydrogel material layer, where it creates a bio-compatible, bacterial protective, fluid absorbing, cushioned skin-like media to facilitate the healing process. Once the burn dressing product has been placed on the burn site, then the dimensionally stable backing member can be removed. The result is a burn dressing containing a bio-compatible, non-irritating, fluid absorbing, skin-like media hydrogel material. Conformity and, more importantly, bacterial protection is improved since there is no "lifting edge" to catch on clothing or bed sheets.

The hydrogel material has healing and absorbing qualities and is preferably a saline solution in an aqueous gel-like phase, which is impregnable within the reticulated layer. The gel-like consistency of the hydrogel material creates a bond between the burn dressing and the burn site without creating an actual adhesive attachment that would damage new cell tissue upon removal. An advantage of the gel-like hydrogel is that it will absorb exudating burn wound fluids. Additionally, it permits clean and neat removal of the burn dressing when the burn heals or the dressing is changed. Finally, since the hydrogel material is transparent, it is possible to inspect the burn site without removing the burn dressing, provided the other layers of the burn dressing product are also transparent. A super-layon as

It is an object of the present invention to provide a burn dressing product containing an aqueous hydrogel substance which is particularly advantageous when used to dress burn sites, by providing a skin-like media which is bio-compatible, non-irritating, fluid absorbing, and bacterial protective; to provide a burn dressing which is more flexible and less bulky than existing dressings; to provide a burn dressing which will not adhere to new cell tissue when it is removed; and to provide a burn dressing product with the above features that is readily available for application to a burn site

In order that the invention may be more readily understood, reference will now be made to the accompanying drawings, in which:

Figure 1 is a plan view of the burn dressing product;

Figures 2A and 2B are cross-sectional views of the burn dressing product and the burn dressing, respectively, of Figure 1 taken along line 2-2.

Figure 3 is an exploded view, illustrating the layers which form the preferred embodiment of the burn dressing product; and

Figures 4A through 4D illustrate the preferred method of application of the burn dressing product of the present invention.

The present invention relates to a burn dressing product for application to a burn site. The burn dressing product is comprised of a burn dressing and a release liner. The invention also includes a method of manufacture and a method of application for the disclosed burn dressing product.

The burn dressing product 10 of the present invention is illustrated in Figures 1, 2A, 2B, and 3. Although the burn dressing product 10 is shown in Figure 1 as having a rectangular shape, it may be any of a variety of desirable shapes. The burn dressing product 10 is composed of several layers including a wound dressing 12, as illustrated by the cross-sectional view of Figure 2A and the exploded view of Figure 3.

Referring now to Figure 2A, the burn dressing product 10 is illustrated in cross-section, taken along line 2-2 of Figure 1. The burn dressing product 10 includes a bacterial barrier layer 14, preferably of polyurethane. The bacterial barrier layer 14 has a first side and a second side, the first side being coated with a bonding agent to form bonding layer 16. The bonding layer 16 preferably comprises a medical grade acrylic adhesive, but may be any suitable bonding means including flame bonding. Attached to the bacterial barrier layer 14 via the bonding layer 16 is a reticulated layer 18, which layer 18 may be any suitable reinforcing material such as reticulated foam, scrim, or non-woven material, the layer 18 having a first side and a second side. The reticulated layer 18 is absorbent enough to permit a hydrogel material 20 to be impregnated in the reticulated layer 18. A hydrogel material layer 22 is then secured by bonding or other means to the first side of the impregnated layer 18. Finally, a release liner 24, preferably silicone coated, overlies the hydrogel material layer 22 and is secured to the first side of the impregnated layer 18 by means of the hydrogel material layer 22. The bacterial barrier layer 14, the bonding layer 16, the impregnated layer 18, and the hydrogel material layer 22 comprise the wound dressing 12, as illustrated in Figure 2B.

. 3

The combination of the impregnated layer 18 and the hydrogel material layer 22 is particularly advantageous for use on burn wounds. The impregnated layer 18 provides a cushion to protect the burn site from external trauma, but does not directly contact the burn site. Instead, to avoid having new cell tissue adhere to the impregnated layer 18, the smooth, gel-like hydrogel material layer 22 directly contacts the wound.

In a further embodiment, the burn dressing product 10 may include a dimensionally stable backing member 26, illustrated in Figures 2A and 3. The backing member 26 is secured to the second side of the bacterial barrier layer 14 by means of an adhesive layer 28. Also in a preferred em-

bodiment of the invention, the bonding layer 16, located between the bacterial barrier layer 14 and the impregnated layer 18, has stronger bonding qualities than the adhesive layer 28, located between the bacterial barrier layer 14 and the dimensionally stable backing member 26. Such a construction allows removal of the dimensionally stable backing member 26 from the burn dressing 12 while maintaining the adhesion between the bacterial barrier layer 14 and the impregnated layer 18.

The present invention provides a method of manufacturing the wound dressing product 10. In the manufacturing method of the present invention, the release liner 24, the impregnated layer 18, and the bacterial barrier layer 14 are provided, each having a first side and a second side. Since the impregnated layer and aqueous hydrogel are pliable, the method of manufacturing the burn dressing product 10 may further include the step of providing the dimensionally stable backing member 26, having a first side and a second side, to maintain the burn dressing 12 in its desired shape until the burn dressing product 10 is applied to a burn site. The first side of the bacterial barrier layer 14 is coated with the bonding agent of the bonding layer 16 and the first side of the dimensionally stable backing member 26 is coated with the adhesive layer 28, which is illustrated in Figures 2A and 3. The second side of the bacterial barrier layer 14, if used in the manufacture of the burn dressing, is then laminated to the first side of the dimensionally stable backing member 26, wherein the adhesive layer 28 is located between the bacterial barrier layer 14 and the dimensionally stable backing member 26, as can be seen in Figure 2A.

Once the layers of the burn dressing product 10 are manufactured; the reticulated layer 18 is impregnated with a clear, gel-like aqueous material 20, preferably hydrogel, which forms a smooth hydrogel material layer 22 on the first side of the impregnated layer 18. After the hydrogel material 20 has been impregnated in the reticulated layer 18, the second side of the release liner 24 is applied to the first side of the hydrogel material layer 22.

The hydrogel material 20 includes from about 15% to about 30% by weight of a polyhydric alcohol selected from a group consisting of polypropylene glycol, polyethylene glycol and glycerine, from about 8% to about 14% by weight isophorone diisocyanate terminated prepolymer, from about 5% to about 10% by weight polyethylene oxide based diamine, up to about 1% by weight of a salt, and the remaining percentage being water. In the preferred embodiment of the present invention, the hydrogel material 20 includes 17% polypropylene glycol, 12% isophorone diisocyanate terminated prepolymer, 9% polyethyl-

ene oxide based diamine, 1% salt, and 61% water. The hydrogel material 20 and the hydrogel material layer 22 provide a bio-compatible, non-irritating, fluid absorbing, bacterial protective, cushioning, skin-like media over the burn site. An additional advantage of the hydrogel is that the hydrogel material 20 and the hydrogel material layer 22 are transparent, making it possible to inspect the burn site without removing the burn dressing, provided the bacterial barrier layer 14, the bonding layer 16, and the impregnated layer 18 are all transparent as well.

Referring now to Figures 4A - 4D, a preferred method of application of the burn dressing product 10 is illustrated in sequence. Figure 4A illustrates how the release liner 24 can be gripped by the person applying the burn dressing product 10, to begin removal of the release liner 24 and expose the hydrogel material layer 22 before the burn dressing product 10 is applied to the burn site. In Figure 4B, the burn dressing product 10 has been flipped over so the hydrogel material layer 22 can contact the burn site 30. The release liner 24 continues to be removed in a rolling motion as the hydrogel material layer 22 is placed over the burn site 30: Once the release liner 24 has been completely removed and the remaining layers of the burn dressing product 10 are properly situated over the burn site 30, the burn dressing product 10 is secured to the burn site 30 by gently pressing into place the burn dressing product 10, as illustrated in Figure 4C: Finally, in one embodiment, as shown in Figure 4D, if the dimensionally stable backing member 26 is used, it is peeled away from the bacterial barrier layer 14, to leave only the burn dressing 12 on the burn site 30.

Once the dimensionally stable backing member 26 has been completely removed, or if the dimensionally stable backing member is not used in the embodiment, only the bacterial barrier layer 14, the impregnated layer 18, and the hydrogel material layer 22, remain on the burn site 30. The result is a burn dressing 12 containing a burn healing hydrogel material layer 22 which gently contacts the burn site 30.

The burn dressing product 10 of the present invention is particularly advantageous for use on exuding burns. In particular, a special feature of the hydrogel material layer 22 is that it retains its gellike integrity even upon removal of the burn dressing 12 from a burn site. The hydrogel material layer 22 does not leave debris in the burn when the burn dressing is removed, nor does it adhere to the burn site. The benefit of this feature is that the hydrogel material layer 22 exhibits a capability of non-traumatically releasing from the burn when the burn dressing 12 is removed, so as not to destroy new cell tissue forming at the burn site. Thus,

15

20

healing is not inhibited by removal of the dressing 12.

Having described the invention in detail and by reference to preferred embodiments thereof, it will be apparent that modifications and variations are possible without departing from the scope of the invention which is defined in the appended claims.

#### Claims

 A method of manufacturing a burn dressing product (10) for a burn wound, comprising the steps of:

providing a release liner (24);

providing a reticulated layer (18), said reticulated layer (18) having a first side and a second side;

providing a bacterial barrier layer (14), said bacterial barrier layer (14) having a first side and a second side;

laminating said second side of said reticulated layer (18) to said first side of said bacterial barrier layer (14);

combining said reticulated layer (18) with a hydrogel material (20), said hydrogel material (20) forming a smooth hydrogel material layer (22) on said first side of said reticulated layer (18);

applying said release liner (24) to said first side of said smooth hydrogel layer (22) \* 31 wherein said smooth hydrogel material layer (22) is located between said reticulated layer (18) and said release liner (24), characterized in that said hydrogel material comprises from 15% to 30% by weight of a polyhydric alcohol selected from the group consisting of polypropylene glycol, polyethylene glycol and glycerine, from 8% to 14% by weight of an isophorone diisocyanate terminated prepolymer, from 5% to 10% by weight of a polyethylene oxide based diamine, up to 1% by weight of a salt, and the balance water, said reticulated layer (18) is sufficiently absorbent to be impregnated with said polyurethane hydrogel material and that said hydrogel material retains its gel-like consistency so as to allow for non-traumatic removal of said burn dressing so as not to destroy new cell tissue forming at a burn site.

- A method of manufacturing a burn dressing product (10) as claimed in claim 1 characterized by said reticulated layer (18) comprising a foam layer.
- A method of manufacturing a burn dressing product (10) as claimed in claim 1 characterized by said reticulated layer (18) comprising a

scrim layer.

- A method of manufacturing a burn dressing product (10) as claimed in claim 1 characterized by said reticulated layer (18) comprising a non-woven material layer.
- A method of manufacturing a burn dressing product (10) as claimed in any preceding claim characterized in that said reticulated layer (18) is secured to said barrier layer (14) by a bonding layer (16).
- 6. A method of manufacturing a burn dressing product (10) as claimed in any preceding claim further characterized by the inclusion of the step of securing a dimensionally stable backing member (26) to said second side of said bacterial barrier layer (14) by means of an adhesive layer (28).
- 7. A method of manufacturing a burn dressing product (10) as claimed in claim 6 characterized by said impregnating step including the step of forming smooth hydrogel material layer. (22) having greater adhesion qualities than said adhesive layer (28) so as to allow removal of said dimensionally stable backing member (26) from said bacterial barrier layer (14) after application of the burn dressing product (10) to the burn while maintaining a bond without actual adhesive attachment between said hydrogel material layer (22) and the skin of a patient.

113 100 A 10

- Product (10) as claimed in claim 6 characterized by said coating step including the step of coating said first side of said bacterial barrier layer (14) with a bonding layer (16) having stronger bonding qualities than said adhesive layer (28) so as to allow removal of said dimensionally stable backing member (26) from said bacterial barrier layer (14) after application of the burn dressing product (10) to the burn while maintaining adhesion between said reticulated layer (18) and said bacterial barrier layer (14).
- A method of manufacturing a burn dressing product (10) as claimed in any preceding claim characterized by said hydrogel material (20) comprising 17% by weight of a polyhydric alcohol selected from a group consisting of polypropylene glycol, polyethylene glycol and glycerine, 12% by weight of an isophorone diisocyanate terminated prepolymer, 9% by weight of a polyethylene oxide based diamine,

10

15

20

30

35

40

45

1% by weight of a salt, and the balance water.

- 10. A burn dressing product (10) for a burn, comprising:
  - a burn dressing including
  - a bacterial barrier layer (14) having a first side and a second side.
  - a reticulated layer (18) combined with a hydrogel material (20) and having a first side and a second side, said second side of said reticulated layer (18) being secured to said bacterial barrier layer (14)
  - a hydrogel material layer (22) on said first side of said reticulated layer (18); and
  - a release liner (24) overlying said hydrogel material layer (22) and secured to said first side of said reticulated layer (18) by means of said hydrogel material layer (22),

characterized in that said hydrogel material comprises from 15% to 30% by weight of a polyhydric alcohol selected from a group consisting of polypropylene glycol, polyethylene glycol and glycerine, from 8% to 14% by weight of an isophorone disocyanate terminated prepolymer, from 5% to 10% by weight of a polyethylene oxide based diamine, up to 1% by weight of a salt, and the balance water, that said reticulated layer (18) is impregnated with said polyurethane hydrogel material, and that said hydrogel material retains its gel-like consistency so as to allow for non-traumatic removal of said burn dressing so as not to destroy new cell tissue forming at a burn site.

11. A burn dressing product (10) as claimed in claim 10 characterized by said reticulated layer (18) comprising a foam layer.

. . . . .

And American States

- 12. A burn dressing product (10) as claimed in claim 10 characterized by said reticulated layer (18) comprising a scrim layer.
- 13. A burn dressing product (10) as claimed in claim 10 characterized by said reticulated layer (18) comprising a non-woven material layer.
- 14. A burn dressing product (10) as claimed in claim 10, 11, 12 or 13, characterized in that said reticulated layer (18) is secured to said barrier layer (14) by a bonding layer (16).
- 15. A burn dressing product (10) as claimed in any of claims 10 to 14, further characterized by the inclusion of a dimensionally stable backing member (26) having an adhesive layer (28), said backing member (26) secured to said second side of said bacterial barrier layer (14) by means of said adhesive layer (28).

- 16. A burn dressing product (10) as claimed in any of claims 10 to 15 characterized by said bacterial barrier layer (14) comprising a polyurethane material.
- 17. A burn dressing product (10) as claimed in claim 10 characterized in that said hydrogel material (20) comprises:
  - 17% by weight of said polypropylene glycol;
  - 12% by weight of said isophorone disocyanate terminated prepolymer;
  - 9% by weight of said polyethylene oxide based diamine;
    - 1% by weight of said salt; and the balance water.

### Patentansprüche

- Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) für eine Brandwunde mit den Stufen, in denen man
  - eine Abziehschicht (24) vorsieht,
  - eine Netzschicht (18) vorsieht, wobei diese Netzschicht (18) eine erste Seite und eine zweite Seite hat,
  - eine Bakterienbarriereschicht (14) vorsieht, wobei diese Bakterienbarriereschicht (14) eine erste und eine zweite Seite hat,
  - die zweite Seite der Netzschicht (18) mit der ersten Seite der Bakterienbarriereschicht (14) laminiert,
  - die Netzschicht (18) mit einem Hydrogelmaterial (20) vereinigt, wobei dieses Hydrogelmaterial (20) eine glatte Hydrogelmaterialschicht (22) auf der ersten Seite der Netzschicht. (18) bildet.
  - die Abziehschicht (24) auf die erste Seite der glatten Hydrogelschicht (22) aufbringt, wobei diese glatte Hydrogelmaterialschicht (22) zwischen der Netzschicht (18) und der Abziehschicht (24) angeordnet wird, dadurch gekennzeichnet, daß das Hydrogelmaterial 15 bis 30 Gew.-% eines aus der Gruppe Polypropylenglycol, Polyethylenglycol und Glycerin ausgewählten mehrwertigen Alkohols, 8 bis 14 Gew.-% eines Vorpolymers mit Isophorondiisocyanatendgruppen, 5 bis 10 Gew.-% eines Diamins auf Polyethylenoxidbasis, bis zu 1 Gew.-% eines Salzes und den Rest Wasser umfaßt, daß die Netzschicht (18) ausreichend absorbierend ist, um mit dem Polyurethanhydrogelmaterial imprägniert zu werden, und daß das Hydrogelmaterial seine gelartige Konsistenz behält, um eine nichttraumatische Entfernung des Verbrennungsverbandstoffes zu gestatten und neues sich auf einer Verbrennungsstelle bildendes Zellgewebe nicht zu zerstören.

7

10

30

35

- Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) nach Anspruch 1, dadurch gekennzeichnet, daß die Netzschicht (18) eine Schaumstoffschicht umfaßt.
- Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) nach Anspruch 1, dadurch gekennzelchnet, daß die Netzschicht (18) eine Mullschicht umfaßt.
- Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) nach Anspruch 1, dadurch gekennzeichnet, daß die Netzschicht (18) eine nicht gewebte Materialschicht umfaßt.
- Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) nach einem der vorausgehenden Ansprüche, dadurch gekennzelchnet, daß die Netzschicht (18) an der Barriereschicht (14) durch eine Bindungsschicht (16) befestigt wird.
- 6. Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) nach der einem der vorausgehenden Ansprüche, weiterhin dadurch gekennzelchnet, daß die Stufe einer Befestigung eines dimensionsmäßig beständigen Unterlageteils (26) an der zweiten Seite der Bakterienbarriereschicht (14) mit Hilfe einer Kleberschicht (28) eingeschlossen ist.

A 5-45

- 7. Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) nach Anspruch 6, dadurch gekennzelchnet, daß die Imprägnierstufe die Stufe einer Bildung einer glatten Hydrogelmaterialschicht (22) mit größeren Haftungsqualitäten als die Kleberschicht (28) einschließt, um so eine Entfernung des dimensionsmäßig beständigen Unterlageteils (26) von der Bakterienbarriereschicht (14) nach Aufbringung des Verbrennungsverbandstoffes (10) auf der Verbrennung gestattet, während eine Bindung ohne tatsächliche Kleberbefestigung zwischen der Hydrogelmaterialschicht (22) und der Haut eines Patienten aufrechterhalten wird.
- 8. Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) nach Anspruch 6, dadurch gekennzelchnet, daß die Beschichtungsstufe die Stufe eines Beschichtens der ersten Seite der Bakterienbarriereschicht (14) mit einer Bindungsschicht (16) mit stärkeren Bindungsqualitäten als die Kleberschicht (28) einschließt, um so eine Entfernung des dimensionsmäßig beständigen Unterlageteils (26) von der Bakterienbarriereschicht (14) nach Aufbringung des Verbrennungsverbandstoffes (10) auf der Verbrennung zu gestatten, während eine Haftung

zwischen der Netzschicht (18) und der Bakterienbarriereschicht (14) aufrechterhalten wird.

- 9. Verfahren zur Herstellung eines Verbrennungsverbandstoffes (10) nach einem der vorausgehenden Ansprüche, dadurch gekennzeichnet, daß das Hydrogelmaterial (20) 17 Gew.-% eines aus der Gruppe Polypropylenglycol, Polyethylenglycol und Glycerin ausgewählten mehrwertigen Alkohols, 12 Gew.-% eines Vorpolymers mit Isophorondiisocyanatendgruppen, 9 Gew.-% eines Diamins auf Polyethylenoxidbasis, 1 Gew.-% Salz und den Rest Wasser umfaßt.
- 10. Verbrennungsverbandstoff (10) für eine Verbrennung mit einem Verbrennungsverbandstoff mit einer Bakterienbarriereschicht (14) mit einer ersten Seite und einer zweiten Seite, einer Netzschicht (18), die mit einem Hydrogelmaterial (20) vereinigt ist und eine erste Seite und eine zweite Seite hat, wobei die zweite Seite der Netzschicht (18) an der Bakterienbarriereschicht (14) befestigt ist, einer Hydrogelmaterialschicht (22) auf der ersten Seite der Netzschicht (18) und einer Abziehschicht (24), die über der Hydrogelmaterialschicht (22) liegt und an der ersten Seite der Netzschicht (18) mit Hilfe der Hydrogelmaterialschicht (22) befestigt ist, dadurch gekennzeichnet, daß das Hydrogelmaterial 15 bis 30 Gew.-% eines aus der Gruppe Polypropylenglycol, Polyethylenglycol und Glycerin ausgewählten mehrwertigen Alkohols, 8 bis 14 Gew.-% eines Vorpolymers mit Isophorondiisocyanatendgruppen, 5 bis 10 Gew.-% eines Diamins auf Polyethylenoxidbasis, bis zu 1 Gew.-% eines Salzes und den Rest Wasser umfaßt, daß die Netzschicht (18) mit dem Polyurethanhydrogelmaterial imprägniert ist und daß das Hydrogelmaterial seine gelartige Konsistenz behält, um so eine nichttraumatische Entfernung des Verbrennungsverbandstoffes zu erlauben und neues sich auf einer Verbrennungsstelle bildendes Zellgewebe nicht zu zerstören.
- Verbrennungsverbandstoff (10) nach Anspruch
  dadurch gekennzeichnet, daß die Netzschicht (18) eine Schaumstoffschicht umfaßt.
- Verbrennungsverbandstoff (10) nach Anspruch
  dadurch gekennzelchnet, daß die Netzschicht (18) eine Mullschicht umfaßt.
- Verbrennungsverbandstoff (10) nach Anspruch
  dadurchgekennzelchnet, daß die Netz-

8

50

10

15

20

1.

40

schicht (18) eine nichtgewebte Materialschicht umfaßt.

- Verbrennungsverbandstoff (10) nach Anspruch
  10, 11, 12 oder 13, dadurch gekennzelchnet, daß die Netzschicht (18) an der Barriereschicht (14) durch eine Bindungsschicht (16) befestigt ist.
- 15. Verbrennungsverbandstoff (10) nach einem der Ansprüche 10 bis 14, weiterhin dadurch gekennzelchnet, daß ein dimensionsmäßig beständiges Unterlageteil (26) mit einer Kleberschicht (28) eingeschlossen ist, wobei das Unterlageteil (26) an der zweiten Seite der Bakterienbarriereschicht (14) mit Hilfe der Kleberschicht (28) befestigt ist.
- 16. Verbrennungsverbandstoff (10) nach einem der Ansprüche 10 bis 15, dadurch gekennzeichnet, daß die Bakterienbarriereschicht (14) ein Polyurethanmaterial umfaßt.
- Verbrennungsverbandstoff (10) nach Anspruch
  dadurch gekennzeichnet, daß das Hy- 25
  drogelmaterial (20)
- 2 Apr 17 Gew.-% des Polypropylenglycols,
- 12 Gew.-% des Vorpolymers mit Isophorondii-
  - 9 Gew.-% des Diamins auf Polyethylenoxidba- 30 sis.
  - 1 Gew.-% des Salzes und den Rest Wasser umfaßt.

# Revendications

 Procédé de fabrication d'un produit de pansement de brûlure (10) pour une blessure de brûlure comprenant les étapes de:

fournir une garniture détachable (24);

fournir une couche réticulée (18), ladite couche réticulée (18) ayant un premier côté et un second côté :

fournir une couche d'arrêt de bactéries (14), ladite couche d'arrêt de bactéries (14) ayant un premier côté et un second côté;

coller ledit second côté de ladite couche réticulée (18) contre ledit premier côté de la couche d'arrêt de bactéries (14);

combiner ladite couche réticulée (18) avec un matériau hydrogel (20), ledit matériau hydrogel (20) formant une couche lisse de matériau hydrogel (22) sur ledit premier côté de ladite couche réticulée (18);

appliquer ladite garniture détachable (24) sur ledit premier côté de ladite couche hydrogel lisse (22), ladite couche lisse de matériau

hydrogel (22) étant située entre ladite couche réticulée (18) et ladite garniture détachable (24), caractérisé en ce que ledit matériau hydrogel comprend de 15 à 30% en poids d'un alcool polyhydrique choisi dans le groupe constitué de polypropylène glycol, polyéthylène alycol et alycérine, de 8 à 14% en poids d'un prépolymère terminé à l'isophorone diisocyanate, de 5 à 10% en poids d'une diamine à base d'oxyde de polyéthylène, jusqu'à 1% en poids d'un sel, et le reste d'eau, ladite couche réticulée (18) étant suffisamment absorbante pour être imprégnée avec ledit matériau hydrogel de polyuréthane et en ce que ledit matériau hydrogel garde sa consistance similaire au gel de façon à permettre un enlèvement non traumatisant dudit produit de pansement de brûlure de façon à ne pas détruire le tissu de nouvelles cellules formé sur le site de la brûlu-

- Procédé de fabrication d'un produit de pansement de brûlure (10) selon la revendication 1, caractérisé en ce que ladite couche réticulée (18) comprend une couche de mousse.
- 3. Procédé de fabrication d'un produit de pansement de brûlure (10) selon la revendication 1, caractérisé en ce que ladite couche réticulée de caractérisé and couche de mousseline.
- 4. Procédé de fabrication d'un produit de pansement de brûlure (10) selon la revendication 1, caractérisé en ce que ladite couche réticulée (18) comprend une couche de matériau non tissé.

er till til er er er er

100

- 5. Procédé de fabrication d'un produit de pansement de brûlure (10) selon l'une quelconque des revendications précédentes, caractérisé en ce que ladite couche réticulée (18) est fixée à ladite couche d'arrêt (14) par une couche de liage (16).
- 45 6. Procédé de fabrication d'un produit de pansement de brûlure (10) selon l'une quelconque des revendications précédentes, caractérisé en outre en ce qu'il comprend l'étape de fixer un élément de renforcement indéformable (26) audit second côté de ladite couche d'arrêt de bactéries (14) au moyen d'une couche adhésive (28).
  - 7. Procédé de fabrication d'un produit de pansement de brûlure (10) selon la revendication 6, caractérisé en ce que ladite étape d'imprégnation comprend l'étape de former une couche lisse de matériau hydrogel (22) ayant des qua-

lités adhésives supérieures à celles de la couche adhésive (28) de manière à permette l'enlèvement dudit élément de renforcement indéformable (26) de ladite couche d'arrêt de bactéries (14) après application dudit produit de pansement de brûlure (10) sur la brûlure tout en maintenant une liaison sans fixation adhésive effective entre ladite couche de matériau hydrogel (22) et la peau d'un patient.

- 8. Procédé de fabrication d'un produit de pansement de brûlure (10) selon la revendication 6, caractérisé en ce que ladite étape d'enduction comprend l'étape d'enduire ledit premier côté de ladite couche d'arrêt de bactéries (14) avec une couche de liage (16) ayant des qualités de liage plus fortes que celles de la couche adhésive (28) de manière à permettre l'enlèvement dudit élément de reforcement indéformable (26) de ladite couche d'arrêt de bactéries (14) après application du produit de pansement de brûlure (10) sur la brûlure tout en maintenant une adhésion entre ladite couche réticulée (18) et ladite couche d'arrêt de bactéries (14).
- 9. Procédé de fabrication d'un produit de pansement de brûlure (10) selon l'une quelconque des revendications précédentes, caractérisé en ce que ledit matériau hydrogel (20) comprend 17% en poids d'un alcool polyhydrique choisi dans un groupe constitué de polypropylène glycol, polyéthylène glycol et glycérine, 12% en poids d'un prépolymère terminé à l'isophorone diisocyanate, 9% en poids d'une diamine à base d'oxyde de polyéthylène, 1% en poids d'un sel, et le reste d'eau.

Level Commence

5 . . .

10. Produit de pansement de brûlure (10) pour une brûlure comprenant :

un pansement de brûlure comprenant une couche d'arrêt de bactéries (14) ayant un premier côté et un second côté,

une couche réticulée (18) combinée avec un matériau hydrogel (20) et ayant un premier côté et un second côté, ledit second côté de ladite couche réticulée (18) étant fixée à ladite couche d'arrêt de bactéries (14),

une couche de matériau hydrogel (22) sur ledit premier côté de ladite couche réticulée (18); et

une garniture détachable (24) recouvrant ladite couche de matériau hydrogel (22) et fixée audit premier côté de ladite couche réticulée (18) au moyen de ladite couche de matériau hydrogel (22), caractérisé en ce que ledit matériau hydrogel comprend de 15 à 20% en poids d'un alcool polyhydrique choisi dans un groupe constitué de polypropylène

glycol, polyéthylène glycol et glycérine, de 8 à 14% en poids d'un prépolymère terminé a l'isophorone diisocyanate, de 5 à 10% en poids d'une diamine à base d'oxyde de polyéthylène, jusqu'à 1% en poids d'un sel et le reste d'eau, en ce que ladite couche réticulée (18) est imprégnée avec ledit matériau hydrogel de polyuréthane, et en ce que ledit matériau hydrogel garde sa consistance similaire au gel de manière à permettre un enlèvement non traumatisant dudit pansement de brûlure de sorte à ne pas détruire le tissu de nouvelles cellules sur le site de la brûlure.

- Produit de pansement de brûlure (10) selon la revendication 10, caractérisé en ce que ladite couche réticulée (18) comprend une couche de mousse.
- 12. Produit de pansement de brûlure (10) selon la revendication 10, caractérisé en ce que ladite couche réticulée (18) comprend une couche de mousseline.
  - 13. Produit de pansement de brûlure (10) selon la revendication 10, caractérisé en ce que ladite couche réticulée (18) comprend une couche de matériau non tissé.
- 14. Produit de pansement de brûlure (10) selon la revendication 10, 11, 12, ou 13, caractérisé en ce que ladite couche réticulée (18) est fixée à ladite couche d'arrêt (14) par une couche de liage (16).
  - 15. Produit de pansement de brûlure (10) selon l'une quelconque des revendications 10 à 14, caractérisé en outre en ce qu'il comprend un élément de reforcement indéformable (26) ayant une couche adhésive (28), ledit élément de renforcement (26) étant fixé audit second côté de ladite couche d'arrêt bactéries (14) au moyen de ladite couche adhésive (28).
- 16. Produit de pansement de brûlure (10) selon l'une quelconque des revendications 10 à 15, caractérisé en ce que ladite couche d'arrêt de bactéries (14) comprend un matériau polyuréthane.
  - 17. Produit de pansement de brûlure (10) selon la revendication 10, caractérisé en ce que ledit matériau hydrogel (20) comprend :

17% en poids dudit polypropylène glycol,12% en poids dudit prépolymère terminéà l'isophorone diisocyanate,

9% en poids de ladite diamine à base d'oxyde de polyéthylène,

40

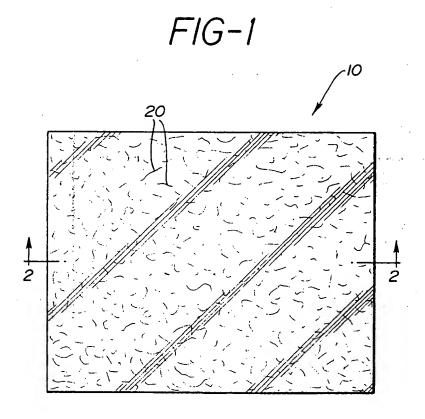
50

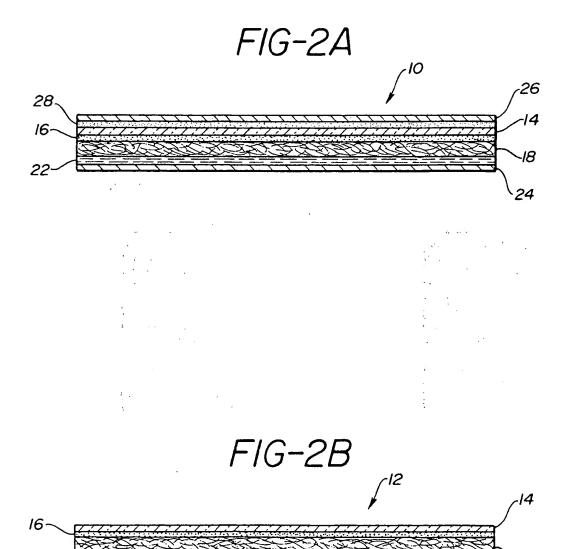
1% en poids dudit sel, et le reste d'eau.

estimated the The first of the control of the cont

1.00

10 mm





22-

